UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Addr ss: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

MK

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/002,485	12/31/97	LAL	P PF-0459US

HM22/0416

MICHAEL C CERRONE
INCYTTE PHARMACEUTICALS INC
3174 PORTER DRIVE
PALO ALTO CA 94304

EXAMINER	
SAOUD, C	
ART UNIT	**PAPER NUMBER**
1646	9

DATE MAILED: 04/16/99

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/022,485	LAL et al.
Examiner	**Group Art Unit**
Christine Saoud	1646

☒ Responsive to communication(s) filed on *Jan 7, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-23* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-23* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

It is noted that the instant application has been restricted. However, it appears that the restriction contained an error regarding an election of species. Claims 1 and 9 are improper Markush claims which recite 77 independent and distinct inventions of polypeptide or nucleic acids. M.P.E.P. § 803.02 provides for restriction of Markush claims and MPEP §803.04 defines nucleic acids as independent and distinct inventions in which "Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 USC 121." The instant claims do not recite a generic claim to a genus of compounds because each nucleic acid sequence encodes a distinct protein, therefore, a species election is not proper.

For the sake of clarity and the benefit of the Applicant, the restriction requirement for each of the distinct inventions is being repeated herein. This will afford Applicant the opportunity to elect the desired invention, traverse this requirement, file a petition, or follow through with whatever action is deemed appropriate. Applicant is further advised that claims 1 and 9 will be objected to because each recites an improper Markush group because the 77 elements recited therein are polypeptides or nucleic acids which do not serve a common function which is based upon a common property or special technical feature not found in the prior art. These polypeptides and nucleic acids are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as a group form structurally related

compounds of the prior art or which provides them with a common utility which is lacking from those prior art polypeptides or nucleic acids.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1 and 15, drawn to a polypeptide, classified in Class 530, subclass 399, for example.

   II. Claims 2-14, drawn to polynucleotides, vectors, host cells, and methods of making proteins, classified in Classes 536 and 435, subclasses 23.1 and 69.1, respectively, for example.

   III. Claim 16, drawn to an antibody, classified in Class 530, subclass 387.1, for example.

   IV. Claim 17, drawn to an agonist of undefined constitution, classified in Class undeterminable, subclass undeterminable.

   V. Claim 18, drawn to an antagonist of undefined constitution, classified in Class undeterminable, subclass undeterminable.

   VI. Claim 19, drawn to a method of treating using a polypeptide, classified in Class 514, subclass 12, for example.

   VII. Claim 20-21, drawn to a method of treating using an antagonist, classified in Class undeterminable, subclass undeterminable, for example.

   VIII. Claim 22-23, drawn to a method detecting a polynucleotide, classified in Class 435, subclass 6, for example.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the polypeptide of Group I could be made by an entirely different method (such as synthetically) rather than by the method of Group I. Group I is independent and distinct from Groups III-V because the polypeptides are materially different from and are therefore independent and distinct from the antibodies of Group III, agonists of Group IV and antagonists of Group V. Although the polypeptides of Group I are necessary to generate the antibodies of Group III, the polypeptides could be used in an entirely different manner, such as in the method of Group VI. Although the polypeptides of Group II are necessary for the method of Group VI, the polypeptides could be used in an entirely different manner, such as in the generation of antibodies of Group III. The polypeptides of Group I, antibodies of Group III, agonists of Group IV and antagonists of Group V have different modes of operation, different functions, and different effects, and are therefore, independent and distinct. The polypeptides of Group I are not required for the methods of Groups VII or VIII, and are therefore, independent and distinct therefrom.

Group II is independent and distinct from Groups II-V because the DNAs, vectors, and host cells are materially different from and are therefore independent and distinct from the antibodies, agonists, and antagonists of Groups III-V. Additionally, the DNAs, vectors, and host cells of Group II are not needed to produce any of the compounds of Groups III-V. Neither are any of the compounds claimed in Groups III-V needed to practice the methods of Group II. The DNAs, vectors, host cells and methods of Group II are independent and distinct from the methods of Groups VI-VII because the methods of Groups VI-VII do not require any part of the invention

of Group II. The DNAs, vectors, host cells and methods of Group II are independent and distinct from the method of Group VIII because although the method of Group VIII uses polynucleotides encompassed by Group II, these polynucleotides can be used in an entirely different manner, such as in the methods of Group II.

3. Group III is independent and distinct from Groups IV-V because the antibodies are materially different from and are therefore independent and distinct from the agonist and antagonist molecules of Groups IV-V. The antibodies of Group III and the compounds of Groups IV-V have different modes of operation, different functions, and different effects, and are therefore, independent and distinct. The antibodies of Group III are independent and distinct from the inventions of Groups Vi and VIII because the antibodies are not required for the practice of the methods of these Groups.

Group IV is independent and distinct from Group V because the agonist has a different mode of operation, different function, and different effect from the antagonist of Group V, and therefore, are independent and distinct. Group IV is independent and distinct from Groups VI-VIII because the agonist molecules of Group IV are not required for practice of the methods of Groups VI-VIII.

4. Group V is independent and distinct from Groups VI and VIII because the antagonist molecules of Group V are not required for practice of the methods of these Groups. Although the antagonist is required for the practice of Group VII, the antagonist could be used in an entirely different method, such as in the generation of antibodies. Groups VI-VIII are

independent and distinct from one another because they are directed to methods which have different goals, method steps and/or starting materials.

The inventions of each named pair can be shown to be distinct because they do not rely upon each other for their ultimate use and they require non-coextensive literature searches. The compounds are structurally different and the methods have different goals, method steps, and/or starting materials. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

5. The claims of Groups I-V are drawn to a multitude of polypeptides, nucleic acids, antibodies, agonist, and antagonist molecules. This constitutes recitation of an implied, mis-joined Markush group that contains multiple, independent and distinct inventions. Each of the different polypeptides/nucleic acids/antibodies/agonist/antagonist molecules are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121.

Upon election of Group I, II, III, IV, or V Applicant is additionally required to elect a single polypeptide, nucleic acid, antibody, agonist or antagonist molecule. This requirement is not to be construed as a requirement for an election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 15, 1999

Christine Saoud, Ph.D.
Christine Saoud
Patent Examiner
Art Unit 1646